

REMARKS

Claims 1-77 and 80-94 are pending in this application. Applicants have amended claims 1, 34, 41, 48, 55, 62 and 77 to recite that the "the antioxidant is selected from the group consisting of an alpha-tocopherol, delta-tocopherol, tocopherol acetate, polydodecyl gallate, octyl gallate, dedecyl gallate, lactic acid and a salt thereof, citric acid and a salt thereof, tartaric acid and a salt thereof, and orthophosphate". Support can be found throughout applicants' specification, including page 22, lines 4-7. This amendment clarifies that applicants are not using flammable hydrogen gas (H₂) as an antioxidant. Applicants also add claims 81-94. Support for which can be found at page 2, lines 28-31, and page 17, line 26, for example.

The Office Action is discussed below:

Obviousness Rejections

On pages 2-5 of the Office Action, the Examiner rejects claims 1-2, 5-19, 21-35, 38-40, and 7 as being unpatentable over Lidgren *et al.* (US 6,448,315) in view of Hahn (US 27,904) and Higgins (US 5,753,182).

On page 6 of the Office Action, the Examiner rejects claim 20 under 35 U.S.C. 103(a) as being unpatentable over Lidgren *et al.* (US 6,448,315) in view of Hahn (US 5,827,904) and Higgins (US, 5753182), and in further view of Parth *et al.* (2002).

On pages 6-7 of the Office Action, the Examiner also rejects claims 3-4 and 36-37 as being unpatentable over Lidgren *et al.* (US 6,448,315) in view of Hahn (US Patent No. 5,827,904), and Higgins (US 5,753,182), and in further view of Burstein *et al.* (US 6,620,198).

On pages 7-10 of the Office Action, the Examiner also rejects claims 41, 42, 45-49, 52-55, 57, 59-62, and 64-72 as being unpatentable over Lidgren *et al.* (US 6,448,315) in view of Hahn (US 5,827,904).

On pages 10-11 of the Office Action, the Examiner also rejects claims 43-44, 50-51, 56, 58, 63 and 73-75 as being unpatentable over Lidgren *et al.* (US 6,448,315) in view of Hahn (US 5,827,904) and in further view of Burstein *et al.* (US 6,620,198).

On pages 11-12 of the Office Action, the Examiner also rejects claims 76 and 80 as being unpatentable over Lidgren *et al.* (US 6,448,315) in view of Hahn (US

5,827,904 and in further view of Burstein *et al.* (US 6,620,198) and Ylanen *et al.* (US 6,517,857

The objections are essentially the same as the rejections set for in the office action dated June 8, 2007. Applicants have responded in detail in the amendment dated September 7, 2007, and that explanation need not be repeated. Applicants discuss the references below in a summary fashion.

- **Lidgren** discloses "antioxidant doping of UHMWPE particles" and that the "antioxidant ... is added to the UHMWPE powder." See column 4, lines 52-63. The Lidgren does not disclose doping of a consolidated/compression molded polymeric material. Furthermore, the doped UHMWPE was found to have a homogeneous distribution of vitamin E. See column 6, lines 65-67. Accordingly, Lidgren does not disclose a gradient. The doped powder of Lidgren is compression molded and irradiated. See column 7, lines 1-5.
- **Hahn** discloses "beta carotene doped UHMWPE powder." See column 3, lines 38-39. This doped powder was melted and compressed using a piston. See column 5, lines 7-17. Doping of bulk UHMWPE with beta carotene also is mentioned. See column 3, line 15. Significantly, Hahn states that beta carotene "can participate in both anti-oxidant as well as pro-oxidative processes". See column 45-46. Moreover, irradiation and cross-linking caused by irradiation are not disclosed by Hahn. Finally, Hahn does not disclose a gradient.
- **Higgins** discloses the use of pressurized hydrogen gas to treat sterilized components. See abstract and column 4, lines 5-9.
- **Burstein** discloses various materials for making knee joints assemblies, and can include polymers. See column 1, line 65 to column 2, line 7.
- **Ylanen** discloses bioactive and porous textile products made from glass fibers. See column 2, lines 49-55.
- **Paasikallio** discloses the mixing of UHMWPE powder with α -tocopherol, followed by sinning for 7 hours at 220°C and 35 bar pressure to produce plates. Samples

from the plates were then subjected to E-beam irradiation. See page 918, sections 2.1 and 2.2.

Applicants have explained that doping of UHMWPE powder with an antioxidant (see Lidgren and Parth) followed by heat consolidation and irradiation results in a decrease in crosslinking of the UHMWPE, which adversely affects wear resistance. See the cited application at page 2, lines 16-22. This problem is only avoided through practice of the claimed invention.

The claims provide for antioxidant doping of consolidated/compression molded polymeric material (before or after formation of the medical implant), but not with the polymeric powder form. The claims also provide for a formation of a gradient of antioxidant in the consolidated/compression molded polymeric material.

The first primary reference cited by the examiner, Lidgren, dopes only powder, and therefore achieves a homogeneous distribution of vitamin E. See Lidgren at column 6, lines 66-77. Thus, Lidgren does not achieve a gradient as recited in the claims, and does not create a consolidated/compression molded material.

The examiner next cites Hahn for the proposition that doping of UHMWPE powder is equivalent to doping of a bulk UHMWPE. Hahn, however, only teaches the use of beta-carotene, which according to Hahn "can participate in both anti-oxidant as well as pro-oxidative processes". See column 45-46. Applicants' claims, however, do not include beta-carotene as an antioxidant. Additionally, Hahn says nothing about a gradient in the beta-carotene doped bulk UHMWPE, and does not teach irradiation of the UHMWPE to form cross-links. Accordingly, Hahn does not supplement or modify Lidgren in any way that is suggestive of the claims, but rather teaches away from the claims by teaching use of a pro-oxidative compound for doping. The skilled person would have no reason to look to Hahn for approaches to prevent oxidation in irradiated polymers because Hahn (i) does not disclose irradiation and its attendant effects and (ii) discloses only a pro-oxidative compound. Teachings away by the cited art are sufficient to rebut an alleged case of obviousness. See *Ecolchem, Inc. v. Southern California Edison Co.*, 227 F.3d 1361, 1372-75 (Fed. Cir. 2000) (reasoning that prior art reference provides no reason to combine to when one of the references teaches away

from the combination). Any charge to the contrary could only be advanced through the use of prohibited selective hindsight. *In re Dow Chemical Co.*, 5 USPQ2d 1529, 1532 (Fed. Cir. 1988) (holding that a specification cannot be used as a guide to reconstruct the state of the prior art).

The remaining secondary references do not rectify the deficiencies of Lidgren and Hahn. Higgins discloses the use of pressurized hydrogen gas to treat sterilized components but hydrogen gas is not an antioxidant according to the claims. Burststein discloses the use of polymeric and non-polymeric parts in prostheses, but that is the sole disclosure that is even remotely germane here. Ylanen discloses textile products made from glass fibers, and does not concern polymeric materials. Parth discloses the mixing of MWPE powder with α -tocopherol, followed by sintering under heat and pressure to produce plates. In this aspect, Parth is essentially cumulative of Lidgren, and thus does not rectify the deficiencies of Lidgren.

Applicants thus submit that a *prima facie* case of obviousness has not been established. The references contain no more than a claim element or so, and some teach away and therefore taken collectively do no more than skirt around the invention rather than suggest it as a whole. The Federal Circuit has held that the citation of many references which skirt around the invention is indicative of patentability, not obviousness. *Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 231 USPQ 81, 93 (Fed. Cir. 1986). *See generally In re Herrick*, 145 USPQ 400, 402 (CCPA 1965). The references individually and collectively, call to mind the Federal Circuit decision of *In re Rouffet*, 198 F.3d 1350 (Fed. Cir. 1998), where the court cautioned:

As this court stated, "virtually all [inventions] are combinations of old elements." *Environmental Designs, Ltd. v. Union Oil Co.*, 713 F.2d 98, 218 USPQ 865, 870 (Fed. Cir. 1983); *see also Richdel, Inc. v. Coal Corp.*, 714 F.2d 1573, 1579-80, 219 USPQ 8, 12 (Fed. Cir. 1983) ("Most, if not all, inventions are combinations and mostly of old elements"). Therefore an examiner may often find every element of a claim in the prior art. If identification of each claimed element in the prior art were sufficient to negate patentability, very few patents would ever issue. Furthermore, rejecting patents solely by finding prior art correlates for the claimed elements would permit an examiner to use the prior invention itself as a blueprint to defeat the patentability of the claimed invention. Such an approach would be an "illogical and inappropriate process by which to determine patentability." *Sensornics*,

Inc. Aerosonic Corp., 81 F.3d 1566, 1570, 38 USPQ2d 1551, 1554
(Fed. Cir. 1996).

To prevent the use of hindsight based on the invention to defeat
patentability of the invention, this court requires the examiner to show
motivation to combine the references that create the case of obviousness.
In other words, the examiner must show reasons that the skilled artisan,
confronted with the same problems as the inventors and with no
knowledge of the claimed invention, would select the elements from the
prior art references for combination in the manner claimed.

In re Roufflet, 149 F.3d 1350, 1357 (Fed. Cir. 1998).

Appellants submit that the rejections do not satisfy the strictures of the *Roufflet*
decision. Secondary references simply do not rectify the deficient and
contradictory teachings of the primary references, and therefore the obviousness
rejections should be withdrawn.

REQUEST

Appellants submit that claims 1-77 and 80-94 are in condition for allowance and
request consideration to that effect. The Examiner is invited to contact the undersigned
at (202) 438-0000 should there be any questions.

Respectfully submitted,



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